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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/638,426	08/12/2003	Samuel J. Epstein	12013/47601	5077

23838 7590 11/18/2008
KENYON & KENYON LLP
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WASHINGTON, DC 20005

EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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11/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/638,426

Applicant(s)

EPSTEIN ET AL.

Examiner

CHRISTOPHER D. KOHARSKI

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 19, 20 and 22-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 19, 20 and 22-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/05/2008 has been entered.

Response to Amendment

Examiner acknowledges the reply filed 08/05/2008 in which claims 1 and 19 were amended and new claims 28-39 were added. Currently claims 1, 19-20, and 22-39 are pending for examination in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-24 and 26-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 23 and 26, the claims reference a "shear-thickening fluid", however independent claim 1 does not reference a shear-thickening fluid, only a non-Newtonian fluid. Regarding claims 24 and 27, the claims reference "the therapeutic", however a therapeutic is not referenced in the

independent claim, only a fluid having therapeutic properties. These above mentioned claims lack antecedent basis for the claimed subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 19-20, 23-24, 26-35 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Nilsson et al. (USPN6,132,405). Nilsson et al. discloses a catheter for peritoneal dialysis.

Regarding claims 1, 19-20, 23-24, 26-35 and 39, Nilsson et al. a device (Figures 3 and 6-7) and method for direct delivery of a non-Newtonian fluid (peritoneal dialysis fluid, col 4, ln 30-36) having therapeutic properties and compounds disposed therein (dialysate fluid) to a target site (peritoneal cavity), the device (28) comprising: a channel (formed via 28) having a proximal end and a distal end and a lumen extending therethrough, the lumen having a longitudinal axis, the channel containing a non-Newtonian fluid having therapeutic properties (dialysate fluid), the channel configured to expose the fluid to a viscosity adjuster, and wherein the viscosity adjuster comprises at least two non-overlapping projections (26, 41, 42) extending perpendicularly from one or more walls of the channel and leaving an open flow channel parallel to the lumen's longitudinal axis, wherein the device further comprises a constricted flow orifice (distal tip 19, 48, 17) and several outflow circular/ovular orifices (21, 22).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsson et al. (USPN6,132,405) in view of Zarate (USPN5,662,619). Nilsson et al. meets the claim limitations as described above except for the viscosity adjuster only being present at the distal of the lumen.

However, Zarate teaches a dialysis needle.

Regarding claims 22 and 25, Zarate teaches a device (12) used to deliver blood the body (Figures 1-4) comprising several non-overlapping projections (26, 28, 30) capable of adjusting the viscosity of the blood only at the distal end (22).

At the time of the invention, it would have been obvious to construct the device of Nilsson et al. with only projections at the distal end in order to control flow at the distal end of the device. The references are analogous in the art and with the instant

invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Zarate (cols 1-2).

Claim Rejections - 35 USC § 103

Claims 36-38 are rejected under 35 U.S.C 103(a) as being unpatentable over Nilsson et al. (USPN6,132,405) in view of Freyman et al. (US2004/0030282). Nilsson et al. meets the claim limitations as described above except for the specific mentioned fluids.

However, Freyman et al. teaches an injection device for control of therapeutic agents.

Regarding claims 36-38, Freyman et al. teaches an agent delivery system (Figures 1-2) that discloses an injection composition consisting of therapeutic drugs ([0023-0024]) and fibrin ([0042]) that can act shear thinning/thickening fluids depending upon the composition ([0079]).

At the time of the invention, it would have been obvious to use the device of Nilsson et al. in order to deliver different fluids as described by Freyman et al. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Freyman et al. ([0003-0008]).

Response to Arguments

Applicant's arguments with respect to claims 1, 19-20 and 22-39 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 11/12/2008

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/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763